MR#347597

Sanitized Copy

August 6, 2012

Via Federal Express

United States Environmental Protection Agency - East
Attn: TSCA Section 8(e) / Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004

Subject: Notice in Accordance with TSCA Section 8(e): Results of an Acute Eye Irritation Study in Rabbits with a Formulation Containing Three Active Ingredients: [redacted] (CAS No. [redacted]) **(Substance 1)** and [redacted] (CAS No. [redacted]) **(Substance 2)** and [redacted] (CAS No. [redacted]) **(Substance 3)**

Dear Section 8(e) Coordinator:

[[redacted]] is submitting results of an Acute Eye Irritation Study in Rabbits with a Formulation Containing Three Active Ingredients: [redacted] (CAS No. [redacted]) **(Substance 1)** and [redacted] (CAS No. [redacted]) **(Substance 2)** and [redacted] (CAS No. [redacted]) **(Substance 3),** conducted by [[redacted]]. The test substance is an experimental pesticide formulation.

The potential of the test substance to cause damage to the conjunctiva, iris or cornea was assessed by a single ocular application of 0.1 mL of the test item to one eye of three White New Zealand rabbits (stepwise procedure starting with one animal and supplementing two additional animals). About 24 hours after application the eye was rinsed with tap water.

The ocular reactions were assessed approximately 1, 24, 48 and 72 hours after application and in weekly intervals until Day 21.

Company Sanitized

Sanitized Copy

The following test item-related clinical observations were recorded during the course of the study:

- Slight to severe corneal opacity (grade 1 to 4)
- moderate iritis (grade 1)
- Slight to obvious conjunctival redness (grade 1 to 2)
- Slight to marked conjunctival chemosis (grade 1 to 3)
- slight to severe discharge (grade 1 to 3)
- Additional findings like milky discharge, small retraction in the eyelid, desquamation of corneal epithelium, vascularization of the cornea in a circumscribed area as well as circular, or injected scleral vessels in a circumscribed or circular area.

In two animals the ocular reactions were reversible within 14 days after application.

The ocular reactions were not reversible in one animal within 21 days after application. Severe corneal opacity (area involved > 0 < ¼), slight conjunctival redness, moderate chemosis, in addition to small retraction in the eyelid, desquamation of corneal epithelium and vascularization into the central part of the cornea in a circumscribed area were still observed in this animal at study termination on Day 21.

Mean scores calculated for each animal over 24, 48 and 72 hours were 2.0, 2.0 and 2.0 for corneal opacity, 1.0, 1.0 and 1.0 for iris lesions, 2.0, 2.0 and 2.0 for redness of the conjunctiva and 2.0, 1.3 and 1.3 for chemosis.

[[redacted]] understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note that a confidential version of this letter is enclosed, treating the chemical identity and company identity as Confidential Business Information.

A Confidentiality Substantiation Questionnaire is being submitted.

Sincerely,

Enclosures